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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,610	09/26/2001	Adam S. Cantor	56032US022	8132

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
03/26/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/965,610	CANTOR ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,16-18,28-31,35-37 and 39-91* is/are pending in the application.

4a) Of the above claim(s) *48-51 and 55-91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,16-18,28-31,35-37,39-47 and 52-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' request for reconsideration filed 01/02/2008.

Claims 1-9, 16-18, 28-31, 35-37 and 39-91 are pending.

Claims 48-51, 55-91 are withdrawn from further consideration.

Claims 1-9, 16-18, 28-31, 35-37, 39-47, and 52-54 are included in the prosecution.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-9, 16-18, 28-31, 35-37, 39-47 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/08229 ('229) by itself or in view of US 5,993,849 ('849).

WO '229 teaches a transdermal drug delivery device comprising a backing and a matrix comprising a copolymer, a softener and a drug (page 2, lines 5-23). The copolymer comprises 40-90% of one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 10 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 10 carbon atoms in the alkyl group and up to 60% of one or more ethylenically unsaturated B monomers copolymerizable with the A monomers. The composition further comprises more than 30% of a macromonomer copolymerizable with the A and B monomers (page 2, lines 5-23). The A monomers are taught on page 4, lines 3-14 with isooctyl acrylate preferred. The B monomers are taught on page 4, line 15 through page 5, line 12, with hydroxyethyl acrylate preferred. The macromonomers are taught on page 5, line 13 through page 8, line 28. Polymethylmethacrylate macromonomers are preferred (page 6, lines 17-18). The softeners of the delivery device affect skin penetration rate and include fatty acids, fatty

alcohols, fatty acid esters such as methyl laurate and tetraglycols (page 8, line 29 - page 10, line 15). Softeners can be included in amounts up to 60% by weight of the matrix (page 10, lines 7-15). WO '229 further contemplates various drugs for delivery by the device including analgesics such as fentanyl (page 12, line 28). The drug is present in the transdermal device in an amount of about 0.01 to about 30 percent by weight (page 13, lines 16-18). Also, the drug is substantially fully dissolved, and the matrix is substantially free of solid undissolved drug (page 13, line 18-20). The transdermal device comprising the pressure sensitive adhesive disclosed by WO '229 allows dissolution of drug and relatively heavy loading with oily excipients, maintains contact with skin, and can be removed cleanly from the skin (page 3, lines 11-15).

Although WO '229 listed fentanyl as a possible acceptable drug for transdermal delivery by the disclosed transdermal copolymer composition, however, WO '229 does not specifically exemplify fentanyl. The reference exemplifies nicotine and levonorgestrel. WO '229 recognized the suitability of fentanyl to be delivered transdermally in an adhesive copolymer of alkyl acrylate monomer and ethylenically unsaturated monomer.

US '849 teaches adhesive composition suitable for transdermal delivery systems and having improved tolerance on the skin and improved controlled release of the active substance (abstract; col.2, lines 15-19). The composition comprises acrylate copolymer and preferred drugs are exemplified by fentanyl and nicotine (claim 10). Therefore the art recognized the equivalency between nicotine and fentanyl in terms of drugs suitable for transdermal delivery from an acrylate copolymer composition.

Therefore, it would have been obvious to one having ordinary skill in the art at the of the invention to provide transdermal delivery composition comprising copolymer of alkyl acrylate monomer and ethylenically unsaturated monomer as disclosed by WO '229, and use the composition to deliver fentanyl, motivated by the teaching of WO '229 that transdermal device comprising the disclosed pressure sensitive adhesive copolymers allows dissolution of drug and relatively heavy loading with oily excipients, maintains contact with skin, and can be removed cleanly from the skin, with reasonable expectation of having transdermal delivery composition comprising copolymer of alkyl acrylate monomer and ethylenically unsaturated monomer and fentanyl wherein the device allows dissolution of fentanyl, as desired by applicants, maintains contact with skin, and can be removed cleanly from the skin.

Additionally one having ordinary skill in the art at the time of the invention would have been motivated to provide transdermal delivery composition comprising copolymer of alkyl acrylate monomer and ethylenically unsaturated monomer as disclosed by WO '229, and use the composition to deliver fentanyl as disclosed by US '849, motivated by the teaching of US '849 that fentanyl is one of the preferred drugs to be delivered in acrylic copolymer adhesive as evident by reciting fentanyl in the claims, motivated by the teaching of US '849 that such a transdermal delivery system has improved controlled release of the active substance with reasonable expectation of having transdermal delivery composition comprising copolymer of alkyl acrylate monomer and ethylenically unsaturated monomer and fentanyl with improved controlled release rate of fentanyl.

Response to Arguments

4. Applicant's arguments filed 01/02/2008 have been fully considered but they are not persuasive. Applicants traverse the standing obviousness rejection by arguing that:

First, '229 is insufficient for one of ordinary skill in the art to have believed with reasonable expectation of success that 8-30% fentanyl would fully dissolve in the claimed compositions. Applicants argue that they had submitted teaching away from any such expectation, which is the article by Roy et al., "Controlled Transdermal Delivery of Fentanyl: Characterizations of Pressure-Sensitive Adhesives for Matrix Patch Design," that disclosed that compositions containing over 4% fentanyl were observed to have dissolved fentanyl and undissolved fentanyl particles. Roy et al. is directly relevant here because it is specifically about fentanyl formulation and clearly teaches away from any general perception of obviousness based the '229 alone.

In response to this argument, it is argued that the formulation disclosed by Roy et al. is not relevant to the present invention as it is not directed to the same copolymer formulation as instantly claimed. Although Roy et al. teaches dissolved and dissolved fentanyl in a formulation, however, it is not formulation comprising the claimed specific copolymer. WO ‘229 teaches the claimed copolymer comprising fentanyl in a concentration encompassing the claimed concentration. WO ‘229 teaches that transdermal device comprising the disclosed pressure sensitive adhesive copolymers allows dissolution of drug. Therefore, the degree solubility of fentanyl in the copolymer

disclosed by the prior art is expected to be the same as instantly claimed copolymer, since compounds and their properties are not separable.

Second, applicants argue that reliance on implied equivalence of fentanyl and nicotine disclosed by US '849 is not appropriate in the present context because nicotine is already a liquid at room temperature (see Table 1 of Naik et al. showing melting point -80°C), so unlike fentanyl (which is a crystalline solid) there would be no possible issue about undissolved nicotine particles remaining. Table 1 of Naik et al., shows aqueous solubility of the two drugs is vastly different (100 mg/ml for nicotine versus only 0.2 mg/ml for fentanyl), so one skilled in the art would never realistically have viewed a disclosure about nicotine formulation as meaningful to understanding formulation of fentanyl.

In response to this argument, it is argued that US '849 is relied upon to show that nicotine and fentanyl are equivalent in the term of both being able to be delivered transdermally, and both being able to be delivered from acrylate copolymer adhesive matrix. The article by Naik et al. demonstrates and compares bioavailability and pharmacokinetics of nicotine and fentanyl but does not show or compare their behavior with acrylate copolymers in order to consider fentanyl and nicotine are distinct and cannot be delivered transdermally using the same polymers. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ

545 (CCPA 1969). The disclosed examples and preferred embodiment do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

Additionally, it has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.,* 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions."

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,139,866 disclosed that fentanyl can be delivered from acrylate copolymer comprising at least two components selected from 2-ethylhexyl acrylate, vinyl acetate, ethyl acrylate, methacrylate, methoxyethyl acrylate, and acrylic acid (abstract; col.2, line 67; col.3, lines 1-5, example 1).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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